### PATENT COOPERATION TREATY

# **PCT**

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Authority under Article 35 and transmitted to the applicant according to Article 36.  2. This REPORT consists of a total of 5 shests, including this cover sheet.  3. This report is also accompanied by ANNEXES, comprising:  a   sent to the applicant and to the International Bureau) a total of sheets, as follows:    sheets of the description, claims and/or drawings which have been amended and are the basis of this re and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).    sheets which supersede earlier sheets, but which this Authority considers contain an amendment that g beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.  b   sheets which supersede earlier sheets, but which this Authority considers contain an amendment that g beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.  b   sheets which supersede earlier sheets, but which this Authority considers contain an amendment that g beyond the disclosure in the international Bureau only) a total of (indicate type and number of electronic carrier(s)), contain sequence slating and/or tables related thereto, in computer readable form only, as indicated in the Suppleme Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).  4. This report contains indications relating to the following items:    Box No. II   Priority    Box No. II   Priority    Box No. IV   Non-establishment of opinion with regard to novelty, inventive step and industrial applicability     Box No. V    Cartain documents cited     Box No. V    Certain documents cited     Box No. V    Certain observations on the international application     Box No. V    Certain defects in the international application     Box No. V    Certain defects in the international application     Date of submission of the demand   Date of completion of this report	Applicant's or agent's file reference NO 7469/WO			FOR FURTHER ACTION See Form PCT//PEA/416				
Asplicant NESTEC S.A.  1. This report is the international preliminary examination report, established by this International Preliminary Examinit Authority under Article 35 and transmitted to the applicant according to Article 36. 2. This REPORT consist of a total of 5 sheets, including this cover sheet. 3. This report is also accompanied by ANNEXES, comprising: a.   sent to the applicant and to the International Bureau) a total of sheets, as follows:					(day/month/year)			
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Box No. II   Priority   Priority   Non-establishment of opinion with regard to novelty, inventive step and industrial applicability   Box No. IV   Lack of unity of invention   Lack of unity of invention   Box No. V   Certain delects in the international application   Box No. VII   Certain delects in the international application   Box No. VIII   Certain observations on the international application   Box No. VIII   Certain observations on the international application   Date of completion of the demand   Date of completion of this report   11.05.2005   29.11.2005   29.11.2005   Name and mailing address of the international application   Certain observations on the international application   Authorized Officer   29.11.2005   29.11.20	×	Box No. I	Basis of the o	pinion				
Box No. IV   Box No. V   Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement				,				
Box No. V Reasoned statement under Article SS(2) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement Box No. VII Certain detects in the international application  Date of submission of the demand  Date of submission of the demand  Date of submission of the demand  Date of completion of this report  29.11.2005  Norms and making address of the informational preliminary assembling authority  European Platent Office - P.B. SSIB Plentlaan 2  No. 2.2001 PM Hilliell' - Page Bas Inception 1 I		Box No. III	Non-establish	ment of opinion with rega	ard to novelty, invent	tive step and industrial applicability		
Box No. VI Certain documents cited		Box No. IV	Lack of unity	of invention				
Box No. VII Certain defects in the international application  Box No. VIII Certain observations on the international application  Date of submission of the demand  Date of completion of this report  11.05.2005  Dame and mailing address of the international profilminary examining authority:  European Platent Office - P.B. 5818 Patentlaan 2  M.1.2920 H Y Rillowit - Payes Bas	⊠	Box No. V						
□ Box No, VIII Certain observations on the international application  Date of submission of the demand  11.05.2005  Name and mailing address of the international preliminary examining authority:  European Platent Office - P.B. 5918 Patentiaan 2  SM 12.2901 Pt Plinkink' - Pare Bas	_							
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11.05.2005  Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5918 Patentlaan 2  SIN_LI-22901 Y Hilliwith - Payer Bas 2		Box No. VIII	Certain obser	vations on the internation	nal application			
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2  Sh LL 2290 HY Rillwill P. Pave Bas	Date of submission of the demand			17.07	Date of completion	of this report		
prellminary examining authority:  European Patent Office - P.B. 5818 Patentiaan 2  N. L. 2280 HV Riiswik - Pays Bas	11.05.2005				29.11.2005			
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	prellminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2				1			

	Box	No. I Basis of the report					
1.	With	n regard to the language, this report is based on the international application in the language in which it was , unless otherwise indicated under this item.					
		This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of: international search (under Rules 12.3 and 23.1(b)) publication of the international application (under Rule 12.4)					
		□ international preliminary examination (under Rules 55.2 and/or 55.3)					
2.	With regard to the elements* of the international application, this report is based on (replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filled" and are not annexed to this report;						
	Des	cription, Pages					
	1-16						
	1-10	do originally lifed					
	Clai	ms, Numbers					
	1-11	as originally filed					
		a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing					
3.		The amendments have resulted in the cancellation of:					
		☐ the description, pages ☐ the claims, Nos.					
		☐ the drawings, sheets/figs					
		☐ the sequence listing (specify): ☐ any table(s) related to sequence listing (specify):					
		3,777					
4.	had	This report has been established as if (some of) the amendments annexed to this report and listed below not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the plemental Box (Rule 70.2(c)).					
		☐ the description, pages ☐ the claims. Nos.					
		☐ the drawings, sheets/figs					
		☐ the sequence listing (specify): ☐ any table(s) related to sequence listing (specify):					
		If item 4 applies, some or all of these sheets may be marked "superseded."					
		if item a applies, some of all of these sheets may be marked "superseded."					

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N) Yes: Claims 1-11

No: Claims

Inventive step (IS) Yes: Claims 1-11 No: Claims

Industrial applicability (IA) Yes: Claims 1-11

No: Claims

2. Citations and explanations (Rule 70.7):

see separate sheet

#### Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: EP-A-0527283

- 1.) The subject-matter of claims 1-11 is new in view of the available prior art.
- 2.) The document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and discloses (the references in parentheses applying to this document) a nutritional composition comprising (per 100 kcal) 10-14,5% of a protein source (casein, milk protein, whey), about 42% of fat, about 44% of carbohydrate and about 3,5 μg TGF-B2 (see cited passages in the search report).

The composition may be used in the treatment or prophylaxis of inflammatory conditions of the gastro-intestinal tract.

The subject-matter of claim 1 therefore differs from this known D1 in that the composition provides 20-30% of the energy of the composition and the composition further comprises free dutamine.

The problem to be solved by the present invention may be regarded as to provide a nutritional composition which is useful for treating or preventing side-effects of chemotherapy and/or radiation therapy (e.g. diarrhoea, increased intestinal permeability).

The solution proposed by the applicant can therefore be regarded as an alternative to D1.

Although the advantages of the a) a higher amount of protein and b) the effect of free glutamine cannot be clearly seen, there is no hint in D1 to introduce these features.

Claim 1 is therefore regarded as inventive.

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (SEPARATE SHEET)

International application No.
PCT/EP2004/011539

Claims 9-11 relate to various uses of the composition according to claim 1 and are also inventive.